of M.P.E.P. § 713.04, Applicants submit the following remarks regarding the substance of that interview.

At the interview, Applicants' representative discussed independent claims 18, 45, 58, and 70 and the claim rejections based on Vetter (DE 42 34 137 A1) and Lederman et al. (U.S. Patent No. 5,800,528) set forth in the Office Actions. More specifically, Applicants' representative proposed amending claims 18, 45, 58, and 70 to recite that the claimed valve is an "in situ" valve in order to obviate the claim rejection based on Vetter. The Examiner agreed that such an amendment to the claims would patentably distinguish from Vetter and would obviate the claim rejection based on Vetter that is set forth in the Office Actions. Applicants' representative further proposed amending claims 45 and 58 to recite that the method of those claims alters a geometry during "systole" in order to obviate the claim rejection based on Lederman et al. The Examiner agreed that such an amendment to the claims would patentably distinguish from Lederman et al. and would obviate the claim rejection based on Lederman et al. that is set forth in the Office Actions.

By this Amendment, Applicants have amended each of claims 18, 45, 58, and 70 in accordance with the agreement reached during the interview. Each of these claims has been amended to recite a method that treats an "in situ" valve, as opposed to removal of an in situ valve and insertion of an artificial *replacement* valve.

Vetter neither discloses nor suggests treating an "in situ" valve in a heart. Rather, Vetter discloses devices that replace an in situ valve with either a prosthetic valve or a transplant valve. To the contrary, as explained in more detail below, Vetter teaches away from the in situ valve treatment, as set forth in claims 18, 45, 58, and 70.

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Vetter discloses a prosthetic transplant valve device designed to *replace* an original existing valve in a heart ventricle. Vetter's device includes plastic fibers (10) extending between a prosthetic valve (2) with seam ring (3) and a plastic patch (8). Vetter teaches the prosthetic valve and seam ring portion of the device as being fixed along the annular valve tissue (that is, the tissue left over after *removal* of the original in situ mitral valve). Thus, the valve and seam ring could not be adapted to fixedly connect to, and thereby treat, the in situ valve since that valve has been removed. Moreover, were the prosthetic valve and seam ring to be secured to an in situ valve, the device would obstruct the valve and cause it to function improperly.

For at least this reason, independent claims 18, 45, 58, and 70, and their respective dependent claims, are patentably distinguishable from Vetter. Applicants therefore request that the rejection of claims 18-30, 45-72, and 75-79 under 35 U.S.C. § 102(b) based on Vetter be withdrawn.

Also by this Amendment, claims 45 and 58 have been amended. Claim 45 has been amended to recite a method that includes, among other things, "altering a geometry of a heart chamber at least during systole." Claim 58 has been amended to recite a method that includes, among other things, "positioning a device . . . such that, at least during systole, a portion of the device contacts and alters a geometry."

According to an aspect, Applicants invention relates to treating a heart valve, such as the treatment of mitral valve insufficiency, for example. Mitral valve insufficiency is a condition whereby the mitral valve does not close properly during the systolic phase of the cardiac cycle in order to prevent blood flow leaking from the left ventricle back into the left atrium. To treat the valve, therefore, an action on the heart

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should occur during systole, which is the portion of the cardiac cycle during which the problem arises.

Lederman et al. discloses a passive girdle that wraps around a heart with a dilated ventricle in order to constrain dilatation of the ventricle during *diastole*. Lederman et al. neither discloses or otherwise suggests a method that acts on any heart structure during *systole.* Indeed, Lederman et al. explicitly discloses at col. 3, lines 4-8 that

> in the present invention a completely passive girdle is wrapped around the ventricle or the entire heart muscle, and sized so that it constrains the dilatation during *diastole* and does *not effect the action of the ventricle during systole*.

(Emphasis added). Thus, Lederman et al. teaches a device and method of treating dilatation of the heart whereby the heart is acted upon during diastole and not during systole.

For at least this reason, claims 45 and 58, and their respective dependent claims, are patentably distinguishable from Lederman et al. Applicants therefore request that the rejection of claims 45, 50, 51, 53-58, 63, 64, and 66-69 under 35 U.S.C. § 102(e) based on Lederman et al. be withdrawn.

In addition to amending the claims, Applicants also have amended the specification to correct the typographical error in the priority data and to update that data, as suggested by the Examiner.

In the Office Actions, the Examiner noted that Applicants did not specifically point out the support in the original disclosure for claims 18-82. Support for claims 18-82, including the amendments to those claims made herein, can be found at least in the specification at page 1, lines 3-7; at page 2, lines 15-22; at page 6, lines 18-25; at page

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7, lines 7-26, at page 8, lines 13-26; and at page 9, lines 1-3, for example. Support also may be found at least in Figs. 4, 9, 15, 16, 19-21 and the corresponding written description of those figures, for example. No new matter has been added by presenting claims 18-82 or by the amendments herein.

A Supplemental Information Disclosure Statement is being filed herewith. Among the documents being submitted in connection with that Supplemental Information Disclosure Statement is a copy of the English language abstract of non-English language document DE 296 19 294, which was submitted with the Information Disclosure Statement filed February 4, 2002. Applicants respectfully request that the Examiner consider the documents cited on the Form 1449 accompanying the Supplemental Information Disclosure Statement and indicate his consideration of those documents by making appropriate notations on the 1449 form.

Dependent claims 19-30, 46-57, 59-69, and 71-79 depend either directly or indirectly from one of independent claims 18, 45, 58, and 70, and, as discussed above, are therefore allowable for at least the same reasons that those claims are allowable. In addition, each of the dependent claims recites unique combinations that are neither taught nor suggested by the cited art, and therefore each also are separately patentable.

The Office Actions contain characterizations of the claims and the related art with which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in the Office Actions.

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Applicants respectfully request the withdrawal of the outstanding claim rejections and objections and the timely allowance of pending claims 18-30 and 45-79.

An Appendix is attached hereto in accordance with the provisions of 37 C.F.R. §§ 1.121(b)(1)(iii) and (c)(1)(ii) to show the changes to the specification and claims as a result of the amendments herein.

Please grant any extensions of time required to enter this Amendment and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Dated: May 28, 2003

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APPENDIX

This Appendix is being provided in accordance with 37 C.F.R. §§ 1.121(b)(1)(iii) and (c)(1)(ii) to show the changes to the specification and claims as a result of this Amendment. Additions are shown by underlined text and deletions are shown by strikethrough text.

Changes to the priority data in the specification:

This is a continuation of U.S. Application No. 08/992,316 ~~08/922, 316~~, filed December 17, 1997, now U.S. Patent No. 6,332,893 B1, which is hereby incorporated by reference.

Changes to the claims:

18. (Amended) A method of treating an in situ heart valve, the method comprising:

providing a first elongate member having a first end and a second end and an anchor assembly at each of the first and second ends;

anchoring the anchor assembly at the first end proximate the in situ heart valve such that at least a portion of the first elongate member between the first end and the second end extends within a chamber of the heart; and

anchoring the anchor assembly at the second end to a portion of the heart spaced from the anchor assembly at the first end,

wherein anchoring the first and second ends of the first elongate member draws together leaflets of the in situ valve.

45. (Amended) A method for treating a an in situ heart valve, comprising:

altering a geometry of a heart chamber at least during systole so as to at least one of

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alter at least a portion of an annulus of the in situ valve;

alter a position of at least one papillary muscle associated with the in situ valve; and

draw together leaflets of the in situ valve.

58. (Amended) A method of treating ~~a~~ an in situ heart valve, the method comprising:

positioning a device with respect to a heart such that, at least during systole, a portion of the device contacts and alters a geometry of structure other than structure of the in situ heart valve so as to at least one of

alter at least a portion of an annulus of the in situ valve;

alter a position of at least one papillary muscle associated with the in situ valve; and

draw together leaflets of the in situ valve.

70. (Amended) A method for improving cardiac function, comprising:

placing a first member relative to a heart chamber to alter the cross-sectional shape of the chamber; and

placing a second member relative to ~~a~~ an in situ valve of the heart chamber to assist in apposition of leaflets of the in situ valve.

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